

Consumer Healthcare Products Association

FDA Part 15 Hearing – Homeopathic Product Regulation

April 20-21, 2015

Docket No. FDA 2015-N-0540

CHPA Mission



Committed to promoting the role of OTC and
Dietary Supplement products through
Science, Education and Advocacy

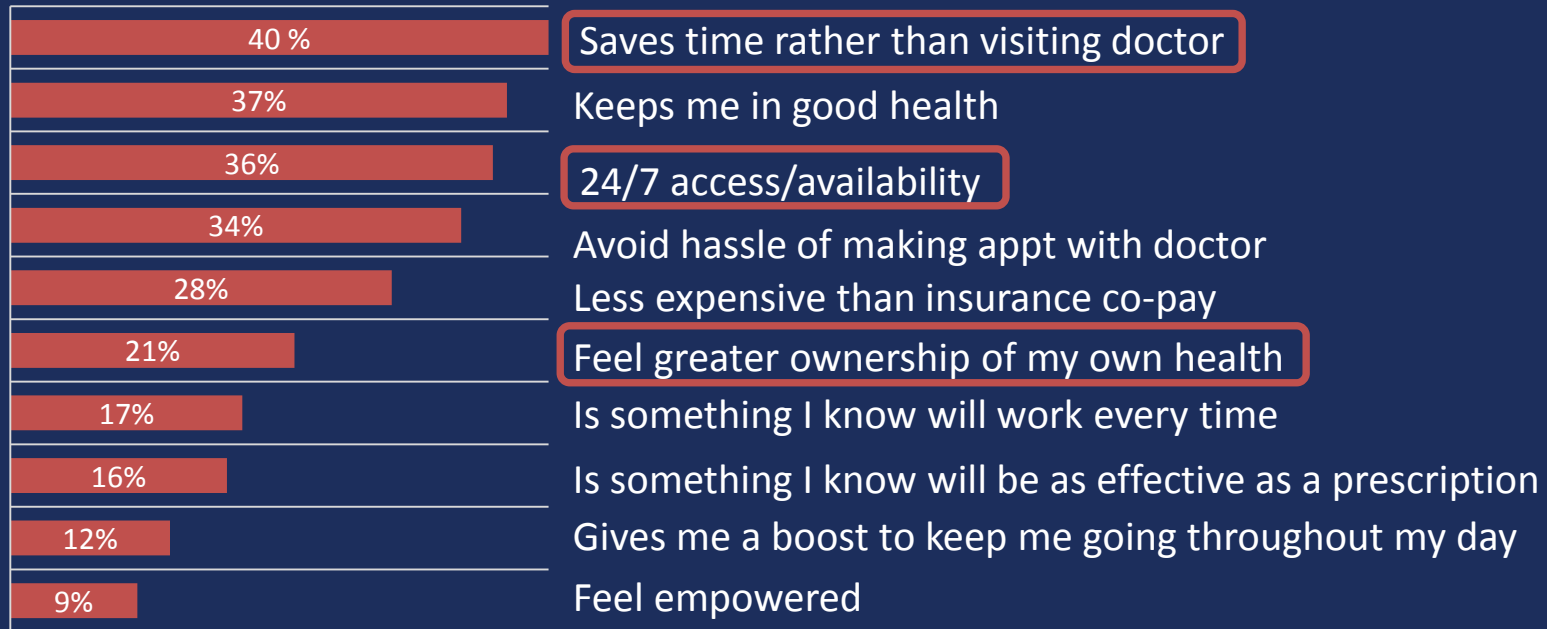
*serving the self-medication
industry since 1881*

Presentation Topics

1. Consumer data and insights (Q1, 8)
2. Homeopathic medicines have a favorable safety profile (Q2)
3. Compliance Policy Guide is a rational framework (Q3)

Convenience, Greater Control Of Health, And Cost Savings

Are Key Benefits Cited For OTC Usage



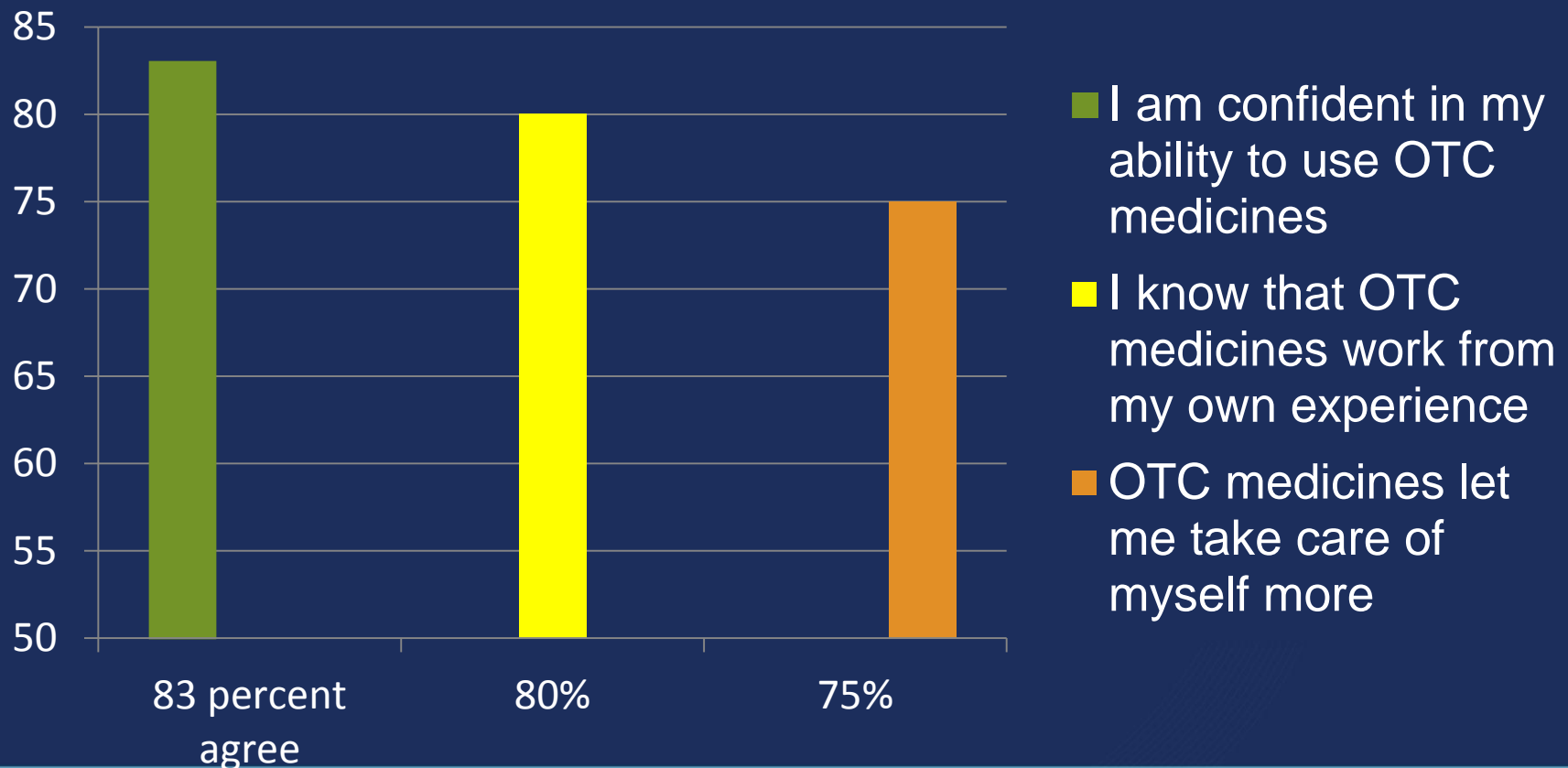
What are the key benefits of self-treatment as it relates to the use of over-the-counter products and being healthy?

% of total respondents, N= 4500

IRI Survey, 2014

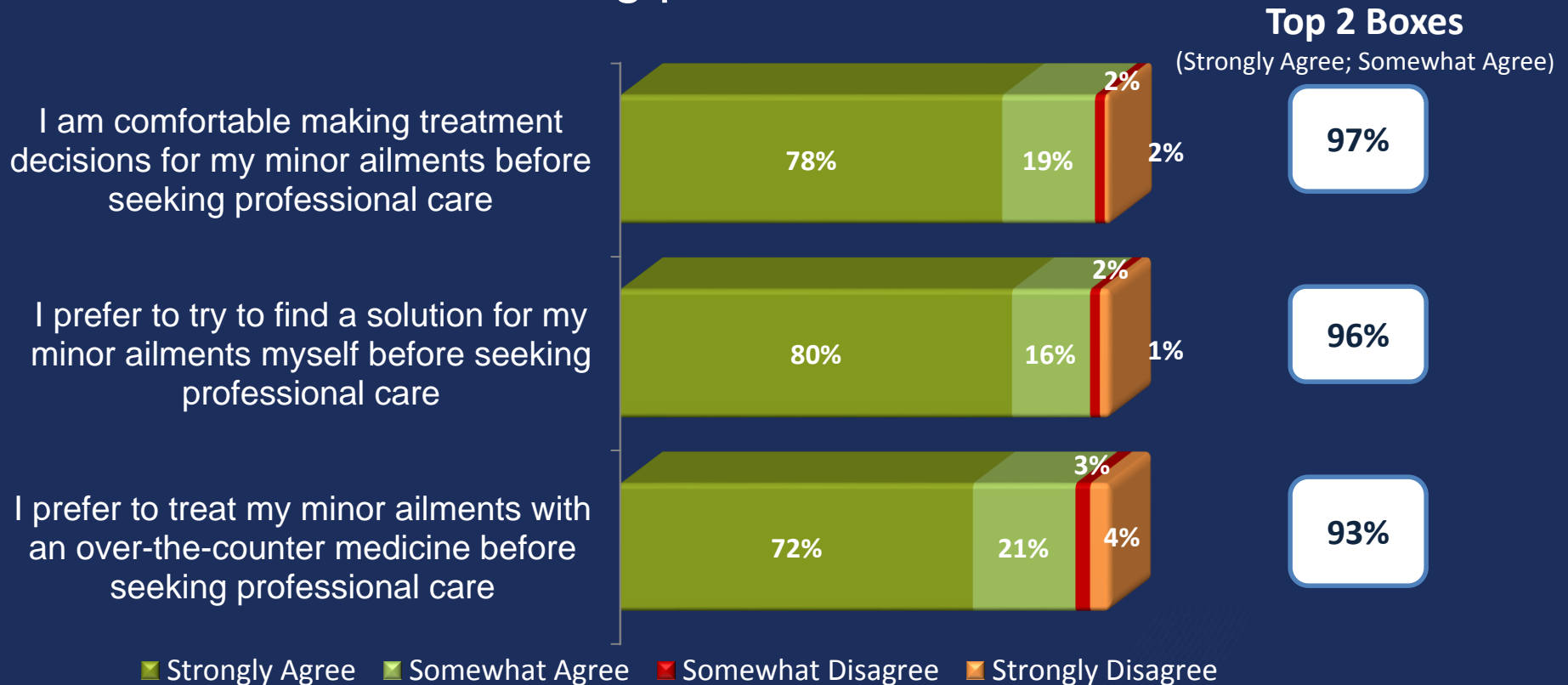
Consumers Report Responsible Attitudes Toward OTC Medicines

Consumers take an active role in their healthcare



Consumers Report Responsible Attitudes Toward OTC Medicines

Most US adults are comfortable treating their own minor ailments before seeking professional care



CHPA Consumer Research on Homeopathic Medicines

- Nationally representative survey of 1,000 US adults
- Conducted by GS Strategy Group
- Fielded questions on
 - consumer familiarity,
 - reported use, and
 - whether consumers want more, less or the same amount of information on homeopathic products.

Consumer Education Efforts Through CHPA Educational Foundation



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Homeopathic Medicines

*Ingredient
Reminders*



What Are Homeopathic Medicines?

Homeopathic medicines contain very small amounts of natural substances derived from plants, minerals, and biological substances, and have been used for more than 200 years to relieve different symptoms. Because of their history of safety, these medicines are often used in treating self-diagnosable conditions, such as the common cold, indigestion, muscle soreness, allergies, and insomnia. Over-the-counter (OTC) homeopathic products are available in many forms, including capsules, creams, eye drops, gels, granules, liquids, lozenges, nasal sprays, ointments, pills, tablets, suppositories, and syrups.

Upcoming CHPA Webinar



Fundamentals of Homeopathy

May 4, 2015 at 1:00 PM EDT, 12:00 PM CDT, 11:00 AM MDT, 10:00 AM PDT (60 minutes)
🕒 Time Zone Converter

Overview

Speakers

Homeopathic medicines contain very small amounts of natural substances derived from plants, minerals, and biological substances, and have been used for more than 200 years to relieve different symptoms. Recent regulatory scrutiny and media coverage have put homeopathic medicines in the spotlight. Join this webinar to hear from three experts on the philosophy behind homeopathy, including its history and current regulation of homeopathic drug products in the U.S. and abroad. Examine the differences and similarities between homeopathic drug products, allopathic drug products, and dietary supplements on issues like claims, labeling, manufacturing, dosage forms, and GMPs. Participants will also learn about the role of the Homeopathic Pharmacopeia of the United States.

Target Audience:

- Sales and Marketing
- Regulatory and Scientific Affairs
- Legal and Policy

Fundamentals of Homeopathy

May 4, 2015 at 1:00 PM EDT, 12:00 PM CDT, 11:00 AM MDT, 10:00 AM PDT (60 minutes)
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Overview

Speakers



J.P. Borneman, Ph.D.
Chairman & Chief Executive Officer Hyland's, Inc.

Borneman was Hyland's president for 10 years before being named to his current post in 2006. He served in a number of positions with the Standard Homeopathic Company, starting as director of marketing and moving through the ranks to achieve the title of chairman and chief executive officer. From 1983-1986, Borneman was vice president of Boiron-Borneman, Inc. He began his career as vice president of John A. Borneman and Sons, Inc.

Borneman's professional affiliations include the American Pharmacists Association, American Chemical Society, Sigma Xi, and the American Public Health Association. He has served as a board member for the International Foundation for Homeopathy. In 2008, he became president of the Homeopathic Pharmacopeia Convention of the United States and has chaired that body's Council on Pharmacy. Borneman is active with the National Association of Chain Drug Stores, the National Center for Homeopathy, the American Homeopathic Pharmaceutical Association, and the American Association of Homeopathic Pharmacists. He was awarded the American Chemical Society's medal for service. He is a trustee of the Southwest College of Naturopathic Medicine, an adjunct associate professor of public health at the University of the Sciences in Philadelphia, and an advisory board member of St. Joseph's University's College of Arts and Sciences. Additionally, Borneman was elected as a governance fellow of the National Association of Corporate Directors.

Borneman has authored numerous papers and is a guest lecturer at many seminars, pharmacy association meetings, and secondary education institutions and universities.



Al Lorman, Esq.
Law Office of Alvin J. Lorman

Lorman opened his own law office in 2007 after 30 years of practice with large national and international law firms. He practices in all areas of food and drug law, biotechnology and health law, trade

Homeopathic Products Have a Very Favorable Safety Profile

- Analysis of poison center data shows low exposures overall
- Most exposures categorized as “no” or “low” effect
- Opportunity to reduce accidental unsupervised exposures, as with all OTC medicines

CHPA 2015

CHPA Supports the Regulatory Framework for Homeopathic Drug Products

- FD&C Act and Compliance Policy Guide provide a framework
- Requirements similar to OTC allopathic drugs:
 - Facility registrations and inspections
 - Drug listing
 - cGMPs
 - Serious adverse event reporting
 - Standardized labeling
 - Compendial standards

Summary

- OTC medicines provide great value
- Consumers are aware of homeopathic products and a majority want more information about them
- Homeopathic products have a very favorable safety profile
- Current regulatory framework provides consumer access and ensures quality standards